

08-17-04



PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

AF
1624
JFW

Applicants: Anthony et al.

Serial No.: 09/973,853

Case No.: 20757Y

Art Unit:

1624

Filed: October 10, 2001

Examiner:

Coleman, Brenda L.

For: AZA- AND POLYAZA-NAPHTHALENYL
CARBOXAMIDES USEFUL AS INTEGRASE
INHIBITORS

Mail Stop AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

RESPONSE AFTER FINAL REJECTION

Sir:

EXPRESS MAIL CERTIFICATE
DATE OF DEPOSIT August 16, 2004
EXPRESS MAIL NO. FL98989347103
I HEREBY CERTIFY THAT THIS CORRESPONDENCE IS
BEING DEPOSITED WITH THE UNITED STATES POSTAL
SERVICE AS EXPRESS MAIL. POST OFFICE TO ADDRESSEE
ON THE ABOVE DATE. ENVELOPE ADDRESSED TO:
COMMISSIONER FOR PATENTS, P.O. BOX 1450,
ALEXANDRIA, VIRGINIA 22313-1450.
MAILED BY: Daria Schepise
DATE: August 16, 2004

This communication is in response to the Office Action mailed July 26, 2004, which set a three-month period for response that expires on October 26, 2004. Claims 1 and 3-37 are pending. Reconsideration is requested.

First Rejection under 35 U.S.C. § 112, first paragraph

Claims 26 and 30 remain rejected under 35 U.S.C. § 112, first paragraph, as not being enabled by the description. This rejection is traversed.

The Examiner is correct that claims 26 and 30 are directed to the inhibition of HIV integrase, and thus the mode of action of the claimed compounds is pertinent. However, it is first pointed out that, as disclosed in Example 193 of the subject application, representative examples of the claimed compounds are active in the HIV integrase strand transfer assay, which is strong evidence that the claimed compounds inhibit integrase. Furthermore, the Rule 132 Declaration by Dr. Daria Hazuda submitted with the amendment filed on May 6, 2004 presents compelling evidence that the claimed naphthyridine compounds (i) are *in vitro* and *in vivo* inhibitors of HIV replication whose mode of action is inhibition of integrase and (ii) are useful for inhibiting integrase. Since submission of the Hazuda Declaration, the studies discussed therein have published as Hazuda et al., *PNAS* 2004, 101 (11): 11233-11238 and Hazuda et al., *Science* 2004,

DO NOT
ENTER
BE 8-25-04